REMARKS

Claims 1, 4, 42, 43, and 45-56 are pending. Claims 1, 4, 42, 43, and 45-56 are rejected under 35 U.S.C. § 112, first paragraph, claims 1 and 50 are rejected under 35 U.S.C. § 112, second paragraph, and claims 1 and 50 are rejected under 35 U.S.C. § 102. Applicants address each of these bases for rejection below.

As an initial matter, Applicants wish to thank Examiners Harris and Helms for the helpful telephonic interview conducted on September 12, 2006. In this reply Applicants present the amendment that Examiners Harris and Helms had indicated would overcome the 35 U.S.C. § 112, second paragraph, rejection, and reiterate, for the record, the arguments in favor of withdrawal of the 35 U.S.C. § 112, first paragraph, and 35 U.S.C. § 102 rejections.

Claim Amendments

Claims 1 and 50 have been amended to recite that the glycoprotein has an apparent molecular weight of about 82 kD *in sodium dodecyl sulfate polyacrylamide gel electrophoresis*. Support for this amendment is found, for example, at page 5, lines 12-18, of the English language specification. No new matter has been added by the present amendment.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 4, 42, 43, and 45-56 are rejected as failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. The Office asserts (page 4):

> It remains unclear what the structure is of the tumor-specific N-linked glycostructure. The art attests to the fact, carboyhydrate moieties are complex.
>
> * * *
>
> In view of Applicants not being able to define, nor characterize the glycostructure one of ordinary skill in the art is not clear on the variability that possibly exists within the genus of glycoproteins.

In support of the complexity of carbohydrate moieties, the Office cites Knight (BioTechnology 7:35-40, 1989; "Knight").

As noted in Applicants' December 5, 2005 reply and as discussed in the September 12, 2006 telephonic interview, Applicants submit that the specification as filed meets the written description requirement for claims 1 and 50, and their dependent claims.

The glycostructure and CD55 amino acid primary structure

Claim 1 is directed to an isolated glycoprotein containing the human amino acid primary structure of CD55 and a tumor-specific N-linked glycostructure. The claim further requires the glycoprotein to have an apparent molecular weight of about 82 kD in sodium dodecyl sulfate ("SDS") polyacrylamide gel electrophoresis and to be a glycoprotein present on adenocarcinoma cell line 23132, but not on a normal cell. Similarly, the glycoprotein of claim 50 is required to contain a section of a glycosylated

human CD55 protein expressed by adenocarcinoma cell line 23132, but not by a normal cell. The glycosylated human CD55 protein has an apparent molecular weight of about 82 kD in SDS polyacrylamide gel electrophoresis, and the section of the glycosylated human CD55 protein includes a tumor-specific N-linked glycostructure. The specification describes the 23132 cell line as being deposited in a public depository[1]. In particular, at page 5, lines 12-18, of the English language text, the specification states:

> In SDS-polyacrylamide-gel electrophoresis ... such a glycoprotein that can be obtained from, for example, human adenocarcinoma cell line 23132 (DSM ACC 201) ... has an apparent molecular weight of about 82 kD.

In the December 5th reply, Applicants noted that, in *Enzo Biochem*, the Federal Circuit has held that one may comply with the written description requirement by publicly depositing the biological material. The Court stated:

> [R]eference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1.

Enzo Biochem, Inc., v. Gen-Probe Inc., 296 F.3d 1316, 1325 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

In *Enzo Biochem*, the deposits were recombinant bacterial cells expressing the DNA molecules of interest. Given that Applicants' specification describes a publicly deposited cell line expressing a glycoprotein having the glycostructure encompassed by the present claims, Applicants submit that the description of the glycostructure in

[1] Applicants note that the DSMZ is included in the list of acceptable depositories provided in M.P.E.P. § 2405.

Applicants' specification meets the standard set forth by the Federal Circuit in *Enzo Biochem*. On this basis alone, the glycostructure recited in the present claims finds sufficient written description in the specification as filed to meet the requirements of 35 U.S.C. § 112, first paragraph.

In addition, as noted in Applicants' December 5th reply, antibodies that recognize the amino acid primary structure of CD55 (DAF) were also available in the art at the time the present application was filed (see, e.g., Hara et al., Immunol. Lett. 37:145-152, 1993; copy enclosed with Applicants' August 30, 2004 reply). In fact, Karnauchow et al. (Journal of Virology 70:5143-5152, 1996; hereafter "Karnauchow") cited by the Office in the present Office Action describes an antibody that binds wild-type CD55 (DAF). These publicly available antibodies allow one skilled in the art to identify and isolate the 82 kD CD55 glycoprotein expressed by the 23132 cell line. For all the above reasons, there can be no question that, at the time of filing, Applicants were in possession of the glycostructure recited in the present claims.

Moreover, as noted in the December 5th reply claim 1 requires the glycoprotein to contain the human amino acid primary structure of CD55. This claim limitation refers to the amino acid sequence of a known protein. The nucleic acid and amino acid sequences of wild-type CD55 (DAF) were publicly known at the time the present application was filed (see, e.g., Caras et al., U.S. Patent No. 5,763,224, issued June 9, 1998, and entitled "Decay Accelerating Factor (DAF) and Nucleic Acids Encoding It; copy enclosed with Applicants' August 30, 2004 reply).

As the sequence of the CD55 primary structure was known at the time of filing, Applicants need not include the CD55 amino acid sequence in the specification. On this point, Applicants, in the December 5th reply directed the Office's attention to the decision by the United States Court of Appeals for the Federal Circuit in *Capon v. Eshhar,* 418 F.3d 1349, 76 U.S.P.Q. (B.N.A.) 1078 (Fed. Cir. 2005). Here, the Federal Circuit stated that "the Board erred in ruling that § 112 imposes a *per se* rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field." *Capon,* 418 F.3d at 1360.

The presently claimed invention is based on the finding that a glycoprotein having the human amino acid primary structure of CD55 and a tumor-specific glycostructure is expressed by tumor cells, but not by normal cells. Following the principles set forth in the *Capon* decision, the amino acid primary structure of CD55 need not be reiterated, described, or reproduced in the instant specification to comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

Claim 50

With respect to claim 50, Applicants, in the December 5th reply, noted that, as shown in Figure 7 of Coyne et al. (J. Immunology 149:2906-2913, 1992; "Coyne;" copy enclosed with Applicants' August 30, 2004 reply), CD55/DAF only contains one N-linked glycosylation site. Given that the sequence of wild-type CD55 and the location of its single N-linked glycosylation site were publicly known at the time the application was

filed, one skilled in the art would recognize which section of CD55 would contain a tumor-specific N-linked glycostructure. Thus, like the amino acid sequence of the human CD55 primary structure, Applicants submit that a description of the only N-linked glycosylation site need not be included in the specification to adequately describe the sections recited in the present claims.

Moreover, claim 50 clearly limits which sections of the CD55 can be included in the claimed glycoprotein. The sections are required to be sections of the 82 kD (in SDS polyacrylamide gel electrophoresis) CD55 protein expressed by publicly deposited cell line 23132 that contain the tumor-specific N-linked glycostructure. As CD55 only contains one N-linked glycosylation site, all sections encompassed by claim 50 must include this glycosylation site.

In sum, in view of the above Federal Circuit decisions, Applicants submit that reference in the specification as filed to a deposit of a cell line expressing a glycoprotein having the glycostructure recited in the present claims provides adequate written description for the glycostructure. Also, given that the sequence of the amino acid primary structure of CD55 and the location, in this sequence, of the single N-linked glycosylation site were known and publicly available at the time of filing, Applicants need not provide these sequences in the specification to adequately describe the CD55 sequences encompassed by the present claims. The 35 U.S.C. § 112, first paragraph, rejection should be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1 and 50 are rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite. Applicants submit that claims 1 and 50, as amended, are free of this basis for rejection. The 35 U.S.C. § 112, second paragraph rejection may be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1 and 50 are rejected under 35 U.S.C. § 102(b) as being anticipated by Karnauchow et al. (Journal of Virology 70:5143-5152, 1996; "Karnauchow"). In particular, the Office states (page 6):

> 75 kD is regarded as being in the range of about 82 kD and the disclosed antibody is specific for the glycostructure.

Applicants respectfully disagree.

As noted in the December 5th reply and in the September 12th interview, Applicants submit that the glycoprotein described by Karnauchow does not have a molecular weight of about 82 kD as required by the claims. Karnauchow states (page 5143, right column):

> Human DAF is a 70- to 75-kDa membrane glycoprotein involved in protecting cells against lysis by homologous complement.

And (page 5146, right column):

> Mab EVR1 reacted specifically with a HeLa cell protein of approximately 70 to 75 kDa that appeared to migrate as a doublet in polyacrylamide gels.

Applicants note that the claims, as amended, recite that the molecular weight of about 82 kD is in SDS polyacrylamide electrophoresis. In SDS polyacrylamide electrophoresis, 70 or 75 kD are not within the range of about 82 kD. As noted in

Applicants' December 5th reply, the specification teaches that Applicants were able to readily distinguish between proteins of approximately 70 kD and approximately 82 kD (see, e.g., page 28, lines 12-22, of the English language specification). Here the specification teaches:

> By altering stringency (1M of NaCl) and with use of membrane preparations, it was possible to detect other proteins with approximately 70 kD and approximately 82 kD (Figure 1a, trace 1).

Figure 1A of Applicants' specification shows a Western blot with several distinct protein bands. The 70 kD band is clearly distinguished from the 82 kD band. Moreover, the specification describes the 70 kD protein as being the "human Lupus p70 auto-antigen protein (gene bank access no. J04611)." Consistent with Applicants' findings, the art also describes the human Lupus p70 auto-antigen as having a molecular weight of approximately 70 kD, as evidenced by Reeves and Sthoeger (J. Biol. Chem. 264:5047-5052, 1989; "Reeves;" copy enclosed with Applicants' December 5th reply). In fact, Reeves readily distinguishes the 70 kD human Lupus auto-antigen from an 80 kD protein (see, e.g., Figure 3).

Moreover, as noted in the September 12th interview, Figure 3 of Karnauchow shows that Karnauchow's EVR1 antibody recognizes a protein that, on an SDS polyacrylamide gel, runs slightly above the 69 kD molecular weight marker and not approximately halfway between the 69 kD and 97.4 kD markers as would be expected of an 82 kD protein. Clearly a 70 kD or 75 kD protein can be distinguished from a protein of about 82 kD using SDS polyacrylamide gel electrophoresis. Applicants submit that

Karnauchow does not describe a glycoprotein of about 82 kD and, therefore, does not describe a glycoprotein that meets all of the limitations of the present claims. The anticipation rejection of claims 1 and 50 over Karnauchow should be withdrawn.

Finally, to clarify the record, in response the Office's assertion at page 6 of the current Office Action that the antibody disclosed by Karnauchow "is specific for the glycostructure," Applicants submit that Karnauchow fails to disclose that its EVR1 antibody binds a glycostructure.

CONCLUSION

Applicants submit that the application is now in condition for allowance, and such action is hereby respectfully requested. If, upon further review, the Office identifies any remaining issues, Applicants respectfully request that the Office contact the undersigned representative telephonically prior to issuance of another Office Action.

Enclosed is a Petition to extend the period for replying to the Office Action for three (3) months, to and including October 11, 2006, and a check for the required fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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